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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,773	03/12/2001	Judah Z. Weinberger	56330-A/JPW/PJP	8786

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Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

14

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,773

Applicant(s)

WEINBERGER, JUDAH Z.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003 and 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. This Office Action is responsive to the Amendment in Response to Final Office Action filed April 14, 2003 and the RCE filed July 9, 2003. The Examiner acknowledges the amendment to the specification; the amendments to claims 1, 8, 22, 25, 28 and 29; and the cancellation of claims 12 and 13. Claim 30 has formally been canceled, although Applicant in the Remarks Applicant indicates that claim 30 has been amended. Claims 1-4, 6-11 and 22-29 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7-10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hess ('466). Hess teaches an apparatus for restenosis treatment of an artery. The apparatus includes a balloon catheter 72 having an inflatable balloon and a cylindrical, elastic radioactive tube 74. The tube is longitudinally slidable over the balloon catheter at least when the tube is placed on the delivery balloon and once the tube is placed at a target site in the body. The cylindrical radioactive tube covers the balloon substantially entirely during inflation such that the outer surface of the tube is exposed for direct contact with the luminal structure. The tube can include a radioactive dose coating or be formed of a mixture of radioactive material additive within non-

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radioactive stent material (col. 4, lines 41-45). The tube can be an expandable and collapsible material such that the tube may be removable (col. 4, lines 37-39). The tube is expandable in a range of sizes. In operation, the balloon catheter is inserted into the body lumen with the radioactive tube having been longitudinally slid over the balloon catheter such that the tube is disposed over the balloon; the balloon is inflated with fluid to expand the tube segment and administer a radiation dose to the luminal structure; the balloon is deflated and the tube segment collapsed; and the balloon catheter and tube are removed from the luminal structure.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess ('466) in view of Lewis et al. ('552). Hess teaches all of the limitations of the claims except that the tube includes a non-radioactive material into which is absorbed radioactive material. Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tube similar that of Hess by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is capable of providing a radioactive dose.

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6. Claims 6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess ('466) in view of Fischell et al. ('282). Hess teaches all of the limitations of the claims except that the balloon is inflated with a gas. Fischell et al. teach a catheter having an expandable radioactive source. The catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). It would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Hess as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

Allowable Subject Matter

7. Claims 25-29 are allowed over the prior art of record.
8. The following is an examiner's statement of reasons for allowance:
- No prior art of record teach or fairly suggest a tube segment for treating a disease process

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as claimed by Applicant in claims 25-29, where the tube segment has varying concentrations of radioactive material for producing a radioactive dose that varies along at least one dimension of the tube segment while having a substantially equal wall thickness along its longitudinal length.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

9. Applicant's arguments filed April 14, 2003 with respect to the rejections under 35 USC 112, second paragraph, have been fully considered and are persuasive. Applicant contends that the amendments filed April 14, 2003 obviate said rejections. This argument is persuasive. As such said rejections under 35 USC 112, second paragraph, have been withdrawn.

Applicant's arguments with respect to claims 1-4, 6-11 and 22-24 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Klein ('284) does not teach or suggest that the tube segment substantially entirely covers the balloon during inflation. This argument has been fully considered but is moot in view of the new grounds of rejection citing Hess set forth hereinabove.

Applicant's arguments with respect to claims 25-29 have been considered and are persuasive. As such, claims 25-29 have been indicated as allowable over the prior art of record.

Applicant's arguments filed April 14, 2003 with respect to the obviousness-type double patenting rejections have been fully considered and are persuasive. Applicant contends that the

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Terminal Disclaimer filed April 14, 2003 obviates said rejections. This argument is persuasive.


As such said double patenting rejections have been withdrawn.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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September 12, 2003